

# Precaution Costs: The Presumption of Breast Cancer Seeding and Its Impact on Surgical Expenditure

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**Summary:** As healthcare costs continue to rise at unsustainable rates (at an average rate of 5.5% a year), expenses without measurable outcomes need review.<sup>1</sup> In reconstructive surgery, empiric change of instruments between oncologic and reconstructive segments of surgery is one such practice. Breast surgery for ductal carcinoma in situ (DCIS), prophylaxis, and partial extirpation has little possible increase in seeding or implantation risk based on the literature. With undue extrapolation from higher risk cancers (such as ovarian), preventative practices of changing out trays, re-gloving, re-gowning, re-preparing, and re-draping between phases persist in operating rooms across the country. From real case costs, the additional expense of 2 surgical setups in the United States is conservatively estimated at \$1232 per case, or over \$125 million per year for this theoretical risk. Using implantation risk for core breast biopsies as a denominator, this cost is \$1.65–\$5.8 million per potential recurrence. This is an unacceptably high cost for hypothetical recurrence risk reduction, especially one that does not impact survival outcomes. (*Plast Reconstr Surg Glob Open* 2020;8:e2903; doi: [10.1097/GOX.0000000000002903](https://doi.org/10.1097/GOX.0000000000002903); Published online 18 June 2020.)

## INTRODUCTION

According to the Centers for Medicare and Medicaid Services, the costs of healthcare in 2017 rose by 4.6%, for a total of 3.5 trillion dollars.<sup>1</sup> Surgical aggregate health care expenditures have risen in tandem, making up an all-time high of 5.8% of gross domestic product in the United States, with an expected increase of 11%–12% in surgical expenditures in the next 5 years.<sup>2</sup> However, increases in expenditure do not always translate into improved outcomes: surgical site infection still accounts for over 20% of nosocomial infections, and venous thromboembolism occurs in 1 out of every 100 patients in the first 90 days postoperation, on average.<sup>3,4</sup> This indicates a disconnection between money spent and improved outcomes. Partially at fault are lingering infection-reduction policies that reflect opinion-based medicine and clinical bias. One such example is the elimination of cloth hats and outside scrubs. In fact, cloth surgeon hats have been scientifically proven to be superior in preventing infection.<sup>5</sup> In the

same vein, our office-based surgical suite has a 0.03% surgical site infection rate despite using “outside” scrubs. Yet, most hospitals (where we operate) store clean scrubs by the bathroom commodes, a practice that incurs its own infection risk from aerosolization.

In oncologic surgery, an additional, yet insufficiently investigated concern lingers: recurrent cancer directly associated with surgical intervention.<sup>6</sup> Operating rooms all over the country take careful precaution to avoid “contamination” that could, in theory, create locoregional neoplasia recurrence. Such measures include changing out trays, re-gloving, re-gowning, re-preparing, and re-draping between the phases of oncologic and reconstructive surgery. It remains unclear whether these precautions are necessary, especially in the national context of increasing surgical care costs and with limited data substantiating this risk. If we measure the costs against presumed outcomes (recurrence and oncologic death), what is the per-recurrence cost of these practices?

## ORIGINS OF THIS “ABUNDANCE OF CAUTION”

These precautions originally stem from discoveries of cancer cells on surgical basins and instruments in Ireland, Germany, and Canada.<sup>7–9</sup> Examination of surgical “wash water” showed cancer cells under a microscope.<sup>7,8</sup> Excision technique aside, there was a logic leap from the presence

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of cancer cells on instruments and gloves to cancer cells re-infiltrating vulnerable tissues, regardless of type, grade, or stage of diagnosis. This notion of “cancer seeding” was fueled by opinion surveys of operating room staffs, citing the prevention of “reimplantation of tumor cells” as akin to antibacterial infection protocol.<sup>10</sup> This metaphor has largely been taken as truth, judging by glove- and tray-change practices in hospital settings. Although concerns over highly implantable tumors may be substantiated, they cannot be empirically extrapolated to solid tumors with no such risk.

These measures seem particularly out of context in breast cancer surgery, where the rates of immediate breast reconstructions have been increasing steadily at 5% per year, with 101,657 breast reconstructions in the United States in 2018 alone.<sup>11,12</sup> Such precautions stand in stark contrast with reality for several reasons: (1) the majority of breast surgery with reconstruction involves the excision of low-staged growths or prophylactic procedures for high-risk patients; (2) as of now, there is no convincing evidence to suggest that breast cancers can successfully circulate, implant, or seed in other anatomical areas<sup>13</sup>; and (3) the cost of these precautions is ultimately passed onto patients and deprives physicians and hospitals of valuable operating time without any proven benefit.

## BIOLOGIC AND EPIDEMIOLOGIC RESEARCH

The disruption of tumor cells after biopsy or needle aspiration is possible due to the lack of cell-to-cell cohesiveness, which is characteristic of tumor cells.<sup>14</sup> These tumor cells are bathed in interstitial fluid, which drains into the lymphatic system and has its own blood supply, and so displacing a loose tumor cell into circulation or tissue fluid is entirely possible.<sup>14</sup> However, 2 components are necessary for cancer seeding to be successful: a biologic propensity for metastasis and a fertile environment with vasculature to support the micrometastases. Seeding requires that the cells leave the primary tumor via intravasation, circulate in blood or lymph, survive, and gravitate via chemical signaling and mechanical force to a fertile environment via extravasation.<sup>15</sup> If the cell is able to take hold, then implantation occurs. Typically, the dissemination of tumor cells occurs only when the tumor is handled inappropriately with poor surgical technique.<sup>15</sup>

Circulating tumor cells often exist in the body long after mastectomy and do not necessarily indicate a recurrence of malignant tumor growth.<sup>16</sup> Of note, breast cancer does not resemble its distant cousin, ovarian cancer, which has been known to seed and requires great precaution.<sup>17</sup> Breast cancer does not seed at clinically significant levels as far as current research has shown.<sup>18</sup>

## HYPOTHESIS

As it stands, this idea of breast cancer reimplantation is based on the mere presence of cancer cells on instruments and gloves following a compromised resection, a nursing staff survey, and no other relevant data. In truth, breast cancer is relatively well contained, with up to 70%–90%

of lumpectomies and mastectomies having clear margins after the initial surgery.<sup>14</sup> Therefore, we hypothesize that 2-field setups are unnecessary and incur undue costs in prophylactic and noninvasive cases. For our purposes, we distinguish noninvasive breast cancers as those that are situated in lobules or ducts and remain relative local to the site (such as lobular carcinoma in situ or ductal carcinoma in situ). Although we are advocating for a reevaluation of current practice for prophylactic and noninvasive cases, we acknowledge that this distinction seems somewhat arbitrary at first glance. Due to the lack of data-driven evidence, research on seeding via breast biopsies serves as the best available approximation in making this recommendation.

## PRELIMINARY RESULTS

Although possible, breast tumor reseeding is a rare occurrence.<sup>19</sup> In a review article by Liebens et al,<sup>14</sup> malignant epithelial cell displacement was found in 22% of needle tract specimens (150/667), but the evidence failed to show a greater risk of recurrence.<sup>20</sup> Similarly, a retrospective review revealed 0.2%–0.7% rates of neoplastic seeding; those with neoplastic seeding had high-grade tumors, triple-negative breast cancers, or multiple-insertion biopsies.<sup>21,22</sup> Likewise, adjusted analyses of 2502 primary breast cancer cases in Austria failed to show significance between preoperative biopsy and breast cancer recurrence (OR, 1.09; 95% CI, 0.85–1.43).<sup>19</sup> Based on the best available evidence from biopsies, even if surgery can “dislodge” tumor cells, it would be unlikely that cell dissemination could occur, barring grossly mistreated margins or careless handling of tumors.

In a review, it was reported that 94% of the tumor seeding cases studied were a result of procedures where breast tumors were involved.<sup>19</sup> Although a seemingly high percentage of all cases, it more likely reflects the prevalence of breast cancer. A review of 15 studies reports that although seeding can occur, there is no statistically significant increased morbidity associated with iatrogenic seeding after procedures such as core needle biopsy, with incidence at 0.005%.<sup>19,23</sup> There is insufficient evidence to demonstrate that any one breast tumor type is more likely to seed than another.<sup>23</sup> Unfortunately, there are little published data with information on the total number of patients undergoing biopsy or the needle procedures in a given period of time and the number of patients actually showing tumor cell seeding among those.<sup>19</sup> Although seeding does occur at a microscopic level, the clinical effect appears negligible: only 3% of biopsies resulted in reseeding, with disease recurrence even rarer and not statistically different from patients who did not undergo biopsy.<sup>16,23</sup> If breast cancer—be it invasive or noninvasive—was easily implantable, seeding from biopsies would be a national crisis.

## METHODS: EXPENDITURE COSTS

Below is an estimated cost breakdown for the delay and associated re-preparing, re-draping, re-gloving, and re-gowning. These estimates are for hospital-based breast reconstruction and come from previous literature

**Table 1. Cost and Quantity of Re-stocked Procedure Supplies**

Item	Unit Price, \$	Amount	Cost, \$
Skin preparation	1.98/30 mL	10 mL	0.66
Polyvinylpyrrolidone (PVP) paint sponge sticks	148.77/30 packs	2 packs	9.92
Sterile gloves	110.53/50 pairs	3 pairs	6.63
Chest/breast pack*	169.66/pack	1	169.66
Saline for basin	1.36/250 mL	250 mL	1.36
Light handle covers	98.94/240 count	2	0.82
Additional gown	148.79/100 gowns	3	4.46
Additional needle, 27 G	8.99/100 count	1	0.09
10 mL syringe: lidocaine with epinephrine	6.72/each	1	6.72
Additional blade, No. 15	25.92/100 count	1	0.26
Newly sterilized surgical trays, soft tissue, and lighted retractor†		1 (minimum)	250
Total for procedure supplies			\$450.58

\*Includes 1 blade, No. 15; 1 specimen container with lid; 1 drape set; 10 gauze; 2 gowns, XL; 10 lap sponges; 1 Mayo stand cover; 1 needle, 18 G; 1 needle counter; 1 skin/utility marker; 1 syringe, 20 mL; 1 syringe, 60 mL; 1 syringe, bulb; 1 suction tubing; 1 table cover; 5 OR towels; 1 Yankauer.

†Includes depreciation.

published on cost-efficacy in surgical technique using national averages (Table 1).<sup>17</sup>

These “precaution fees” add to a grand total of \$1231.83 per surgery, a conservative estimate depending on the minimal staffing of the case, the cost associated with the specific surgeon’s preference card, and the geographic location of the hospital (Table 2). These costs have the potential to rapidly escalate with additions of co-surgeons or use of specialized instruments. These estimations exclude the costs of intravenous drugs administered by the anesthesiologist during such time, as pricing is highly dependent on the market, hospital purchasing practices, and anesthesiologists’ discretion.<sup>25</sup>

We appreciate that practice patterns vary and centers that practice evidence-based medicine often use the same setups, thus limiting the cost of cases. As there were 101,657 breast reconstructions performed in 2018 in the United States, this precautionary tale could create a \$125 million burden on the healthcare industry annually if all breast cancer cases were handled in this manner.<sup>12</sup> Unfortunately, as mentioned previously, there are no data on the widespread practices of hospitals, and this is assumed as a relatively universal practice, in line with our experiences.

To contextualize this number, we seek to estimate the per-recurrence cost of these practices. Of the 101,657 breast reconstruction cases in 2018, approximately 10,000 were entirely prophylactic in nature (18 out of every 1000 mastectomies are bilaterally prophylactic, and 80% of women with prophylactic mastectomies get reconstruction).<sup>12,26,27</sup> Excluding this population, we are left with

approximately 90,000 cases of breast cancer with reconstruction. According to the American Cancer Society, only 12% of breast cancers in 2018 were triple-negative, leaving 10,800 patients at increased risk for reseeding and subsequent recurrence.<sup>28</sup> Assuming that the evidence from needle track seeding is correct, there is a worst possible rate of 0.2%–0.7% for neoplastic seeding, most evident in triple-negative patients.<sup>21,22</sup> Therefore, 22–76 patients each year are at high risk for neoplastic seeding. Extrapolated, the costs of maintaining such practices are \$1.65–\$5.8 million per recurrence.

## DISCUSSION

A growing subsection of reconstructive surgery involves breast reconstructions of various natures (autologous tissue transfer, alloplastic, or both), with a 39% increase in breast reconstruction surgery from 2000 to 2017.<sup>29</sup> An increasing number of oncologic reconstructions, or quadrantectomies, are performed immediately following extirpation. In hospital systems in major metropolitan areas (such as those in Washington, D.C., and Manhattan), the practice of exchanging instrument trays, re-draping, re-preparing, and exchanging gowns and gloves between the resection and reconstruction is seen as the “best practice.” This practice is considered so critical that multiple hospital systems where we operate are resistant to eliminating 2-field setups in the wake of the COVID-19 outbreak, despite severe shortages in essential supplies. In addition, the plastic surgeon waits longer before starting surgery, precious OR time is used, the time under anesthesia increases, and ultimately, the cost of the surgery surges. The nonquantifiable loss in these situations is the intraoperative distraction of the scrub and circulator during this exchange.

These precautions stem from the false premise that breast cancer seeds easily, and reimplantation of cancer cells is always a possibility for every cancer excision. This train of thought reflects policies and hospital cultures that are out of touch with scientific reality. It draws a nonexistent parallel between a tumor and an infection and mirrors infection-control protocols. Based on the numbers, these preventative practices amount to a per-recurrence cost between \$1.65 and \$5.8 million, a value that vastly exceeds the estimated \$150,000 per quality-adjusted life year that policymakers and citizens are willing to pay.<sup>30,31</sup>

**Table 2. Variable Resources (with Cost Dependent upon Geographic Location, Staffing Norms, and Surgeons’ Preference Cards) for 15 Minutes of Additional Turnover**

Resource	Quantity	Cost per Hour, \$	Turnover per 15 min, \$
Operating room	1	2220 <sup>24</sup>	555.00
Surgeon	1 (2, depending on case)	500	125.00
Anesthesiologist	1	315	78.75
Nursing/technologist staffing	2 (3, depending on case)	45	22.50
Total for variable resources			781.25
Total cost			1231.83

Having said that, one may argue in favor of these precautions for the sole sake of infection prevention, particularly in implant-based reconstructions. We have already extensively studied and published on infection control in breast tissue.<sup>32,33</sup> Of course, the breast case becomes inherently colonized over the course of the surgical procedure; however, the sources of the infectious agents are the nipple ducts and axilla, not the instruments. We have found no evidence in the literature to suggest that changing instruments leads to a decrease in surgical site infection rates.<sup>34</sup> In fact, in gynecomastia excision surgery in males where the same surgical field and instruments are maintained throughout the procedure, the infection rate is <1%.<sup>35</sup> Without prospective studies (eg, evaluating re-preparing both the internal and external field with betadine, a \$2 solution, against a whole field change), this is again a presumptive precaution.

In the US medical arena, no discussion on rationing of resources or changes to presumed “best practices” deemed important by advisory groups like the Association of PeriOperative Registered Nurses (AORN) or the Joint Commission on Accreditation of Healthcare Organizations (JACHO) is complete without mentioning malpractice. This cost containment is suggested for an outcome (seeding) that has no effect on tumor mortality. Since the best available evidence demonstrates no long-term harms, the argument of malpractice is mute.

## CONCLUSIONS

American healthcare costs continue to sky-rocket in a culture of inferred risk and malpractice aversion, which influences decision making. In this case, the byproduct is a \$125 million surgery-specific surcharge to reduce a hypothetical risk, extrapolated from fundamentally different tumor biology. This practice of changing instruments and re-preparing between the ablative breast and reconstruction teams reflects anecdotal and committee-based medicine. Given the dearth of evidence-based medicine, the cost is not merited. The aversion to change of current opinion-based practices was no more evident to us than during the COVID-19 pandemic.<sup>31</sup>

In our opinion, the literature on breast cancer seeding is marginal at best and does not merit the sunk costs of these unnecessary measures, which are ultimately passed onto patients and result in lower payouts for physicians and hospitals alike. With the goal of reducing surgical costs, inpatient and outpatient settings alike should reevaluate their current policies and procedures. Unless further research can definitively point to breast cancer seeding as an actual phenomenon that occurs in a measurable percentage of mastectomy to reconstruction cases, it is a waste of time, money, and resources to extrapolate infection control protocols to breast cancer recurrences.

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